

PATENT APPLICATION

**DEVICE AND METHOD FOR MODIFYING
THE SHAPE OF A BODY ORGAN**

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Express Mail Label No. EV 333 489 151 US

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CROSS-REFERENCE

- [0001]** This application claims the benefit of U.S. Provisional Application No. 60/476,693, filed June 5, 2003, which application is incorporated herein by reference.

BACKGROUND OF THE INVENTION

- [0002]** The mitral valve is a portion of the heart that is located between the chambers of the left atrium and the left ventricle. When the left ventricle contracts to pump blood throughout the body, the mitral valve closes to prevent the blood from being pumped back into the left atrium. In some patients, whether due to genetic malformation, disease or injury, the mitral valve fails to close properly causing a condition known as regurgitation, whereby blood is pumped into the atrium upon each contraction of the heart muscle. Regurgitation is a serious, often rapidly deteriorating, condition that reduces circulatory efficiency and must be corrected.
- [0003]** Two of the more common techniques for restoring the function of a damaged mitral valve are to surgically repair the valve, replace the valve with a mechanical valve, or to suture a flexible ring around the valve to support it. Each of these procedures is highly invasive because access to the heart is obtained through an opening in the patient's chest. Patients with mitral valve regurgitation are often relatively frail thereby increasing the risks associated with such an operation.
- [0004]** One less invasive approach for aiding the closure of the mitral valve involves the placement of a support structure in the cardiac sinus and vessel that passes adjacent the mitral valve. The support structure is designed to push the vessel and surrounding tissue against the valve to aid its closure. This technique has the advantage over other methods of mitral valve repair because it can be performed percutaneously without opening the chest wall. Examples of such devices are shown in U.S. Patent Appl. S.N. 10/003,910, "Focused Compression Mitral Valve Device and Method;" U.S. Patent Appl. S.N. 10/142,637, "Body Lumen Device Anchor, Device and Assembly;" U.S. Patent Appl. S.N. 10/331,143, "System and Method to Effect the Mitral Valve Annulus of a Heart;" and U.S. Patent Appl. S.N. 10/429,172, "Device and Method for Modifying the Shape of

a Body Organ,” filed May 2, 2003. The disclosures of these patent applications are incorporated herein by reference.

[0005] The purpose of a support device in a lumen such as a vein or artery is to reshape a particular tissue area adjacent to the lumen. In order to be minimally invasive, the reshaping should be limited to the target tissue, such as the mitral valve annulus, and any reshaping of other tissue adjacent to the lumen should be minimized or avoided. For example, to treat mitral valve regurgitation, the device is placed in the coronary sinus to reshape the mitral valve annulus. Care should be taken to minimize the reshaping of other adjacent tissue, such as nearby arteries. See, e.g., the following applications (the disclosures of which are incorporated herein by reference): U.S. Patent Appl. S.N. 09/855,945, “Mitral Valve Therapy Device, System and Method” (published November 14, 2002, as US 2002/0169504 A1); U.S. Patent Appl. S.N. 09/855,946, “Mitral Valve Therapy Assembly and Method” (published November 14, 2002, as US 2002/0169502 A1). It is also advisable to monitor cardiac perfusion during and after such mitral valve regurgitation therapy. See, e.g., U.S. Patent Appl. S.N. 10/366,585, “Method of Implanting a Mitral Valve Therapy Device,” the disclosure of which is incorporated herein by reference.

SUMMARY OF THE INVENTION

[0006] One aspect of the invention is a tissue shaping device adapted to be deployed in a lumen to modify the shape of target tissue adjacent to the lumen. In one embodiment the device includes first and second anchors; a connector disposed between the first and second anchors; and a focal deflector disposed between the first and second anchors and may be adapted to extend away from the lumen axis and toward the target tissue and/or away from the lumen axis and away from the target tissue when the device is deployed in the lumen. The focal deflector may have an expandable portion that is, e.g., self-expanding or expandable through the application of an actuation force. The device may also have a lock to lock the focal deflector in an expanded configuration.

[0007] In some embodiments the focal deflector is integral with the connector. For example, the focal deflector may be a bend in the connector, such as a bend that extends away from the lumen axis and toward the target tissue. The focal deflector may include a local change to the linear shape of the connector, such as a portion of increased curve of the curved line of the connector. The focal deflector may also include a flattened portion of the connector.

[0008] In some embodiments the focal deflector includes an expandable anchor and possibly a portion integral with the connector and adapted to extend away from the lumen axis and toward the target tissue when the device is deployed in the lumen.

[0009] Another aspect of the invention is a method of modifying target tissue shape. The method includes the steps of providing a tissue shaping device comprising proximal and distal anchors, a connector disposed between the proximal and distal anchors, and a focal deflector; placing the tissue shaping device in a lumen adjacent the target tissue; applying a shaping force from the focal deflector against a lumen wall to modify the shape of the target tissue; and expanding the proximal and distal anchors to anchor the device in the lumen. In some embodiments the expanding step includes the steps of expanding the distal anchor to anchor within the lumen; applying a proximally directed force on the device; and expanding the proximal anchor while applying the proximally directed force.

[0010] In some embodiments, the placing step includes the step of orienting the focal deflector away from the lumen axis and toward the target tissue. In other embodiments,

the placing step includes the step of orienting the focal deflector away from the lumen axis and away from the target tissue.

[0011] The applying step may include the step of expanding the focal deflector, such as by applying an actuation force to the focal deflector. The focal deflector may also be locked in its expanded configuration. In some embodiments the applying and expanding steps may include expanding the distal anchor to anchor within the lumen; applying a proximally directed force on the device; expanding the focal deflector while applying the proximally directed force; applying a proximally directed force on the device after expanding the focal deflector; and expanding the proximal anchor while applying the proximally directed force of the previous step.

[0012] Yet another aspect of the invention is a tissue shaping device adapted to be deployed in a lumen to modify the shape of target tissue adjacent to the lumen. In some embodiments the device includes an expandable anchor; a focal deflector; a connector disposed between the anchor and the focal deflector; and a tail extending from the focal deflector away from the anchor. The focal deflector may include an expandable portion. In some embodiments, the focal deflector is adapted to extend away from the lumen axis and away from the target tissue when the device is deployed in the lumen.

[0013] One application for the device of this invention is in the treatment of mitral valve regurgitation. The invention will be described in further detail below with reference to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Figure 1 shows a tissue reshaping device according to one aspect of the invention deployed in a coronary sinus to reshape the mitral valve annulus to treat mitral valve regurgitation.

[0015] Figure 2 is a perspective view of the device shown in Figure 1.

[0016] Figure 3 shows another embodiment of the invention.

[0017] Figure 4 shows another embodiment of the invention and its use to treat mitral valve regurgitation.

[0018] Figure 5 is a perspective view of the device shown in Figure 4.

- [0019] Figure 6 shows an embodiment in which the focal deflector faces in the same direction as the anchors.
- [0020] Figure 7 shows yet another embodiment of the invention deployed in a coronary sinus to reshape the mitral valve annulus to treat mitral valve regurgitation.
- [0021] Figure 8 is a perspective view of the device shown in Figure 7.
- [0022] Figure 9 shows yet another embodiment of the invention.
- [0023] Figure 10 shows still another embodiment of the invention.
- [0024] Figure 11 shows the focal deflector of the embodiment of Figure 10.
- [0025] Figure 12 is yet another view of the focal deflector of the embodiment of Figure 10.
- [0026] Figure 13 shows yet another embodiment of the invention.
- [0027] Figure 14 shows an embodiment of the invention with a tail portion extending from the focal deflector.

DETAILED DESCRIPTION OF THE INVENTION

- [0028] Tissue shaping devices that apply force to a localized, discrete portion of the vessel wall surrounding a lumen have been described. See, e.g., U.S. Patent Appl. S.N. 10/003,910, "Focused Compression Mitral Valve Device and Method," which describes the use of such devices disposed in the coronary sinus to treat mitral valve regurgitation. Other therapies deploy one or more rigid devices in the lumen to change the shape of the lumen and adjacent tissue. See, e.g., Lashinski et al. U.S. Patent Appl. SN 10/066,302 (published as US 2002/0151961 A1); Taylor et al. U.S. Patent Appl. SN 10/068,264 (published as US 2002/0183835 A1); Liddicoat et al. U.S. Patent Appl. SN 10/112,354 (published as US 2002/0183838 A1); the disclosures of which are incorporated herein by reference. Still other tissue shaping devices utilize an "anchor and cinch" method to modify tissue adjacent a lumen, i.e., by anchoring a distal anchor, placing a proximally-directed force on a connector extending proximally from the distal anchor, and anchoring a proximal anchor before ceasing the proximally directed force to maintain the device's configuration and the reshaping of the tissue.
- [0029] The present invention provides a device disposed in a lumen to reshape tissue adjacent to the lumen that includes a focal deflector tissue reshaper, two anchors and an

optional connector to help maintain the position of the focal tissue reshaper within the lumen. The use of a focal deflector tissue reshaper aimed at target tissue adjacent to the lumen minimizes the risk of adverse consequences from altering the shape of non-target tissue adjacent to other parts of the lumen. The anchors and/or connector may also be used to help reshape the target tissue.

[0030] Figures 1 and 2 show a tissue reshaping device 10 according to one aspect of this invention. Device 10 is designed to be disposed in the coronary sinus or other cardiac vein to treat mitral valve regurgitation. It should be understood that such devices may also be used in other body lumens to reshape other tissue.

[0031] As shown in Figures 1 and 2, device 10 has a proximal anchor 12 and a distal anchor 14 connected by a connector 15. In the embodiment shown in Figures 1 and 2, the anchors 12 and 14 are formed from metal wire, preferably made from a shape memory material such as nitinol, bent into a figure 8 configuration. Crimps 16 and 18 hold the wire in place and attach the anchors to connector 15. In the embodiment shown in Figure 1, crimps 16 and 18 are formed from wound wire, such as nitinol. In the embodiment shown in Figure 2, crimps 16 and 18 are formed from metal tubes, such as titanium tubes.

[0032] Device 10 is delivered via a catheter to the treatment site within the lumen in a collapsed or unexpanded configuration. After expelling device 10 from the catheter at the treatment site (either by advancing the device distally out of the end of the catheter or by moving the end of the catheter proximally while maintaining the device stationary), the device's anchors begin to self-expand. At the proximal end of each anchor is an eyelet 20 and 22. Advancing eyelets 20 and 22 distally over corresponding lock bumps 24 and 26 further expands and locks the anchors 12 and 14 in an expanded configuration. Further details of the construction, delivery and deployment of such anchors may be found in U.S. Patent Appl. S.N. 10/142,637, "Body Lumen Device Anchor, Device and Assembly;" U.S. Patent Appl. S.N. 10/331,143, "System and Method to Effect the Mitral Valve Annulus of a Heart;" and U.S. Patent Appl. S.N. 10/429,172, "Device and Method for Modifying the Shape of a Body Organ," filed May 2, 2003. It should be understood that other anchor designs could be used without departing from the invention.

[0033] Device 10 has a focal deflector 28 facing away from the anchors 12 and 14 and toward the mitral valve annulus. In this embodiment, focal deflector 28 is formed as a bend in the connector 15. As shown in Figure 1, when disposed in lumen 30 (shown here as the coronary sinus), the orientation of device 10 places focal deflector 28 against the target tissue 37 to reshape the mitral valve annulus 38. Device 10 may be curved to help ensure this orientation. For delivery via a catheter, focal deflector 28 is deformed and assumes the shape shown in Figure 1 and 2 after deployment from the catheter.

[0034] Because of the action of focal deflector 28, the desired reshaping of the mitral valve annulus may be achieved with less cinching than other device designs or even with no cinching. Thus, the anchors do not need to anchor as tightly and may be expanded less, thereby minimizing the reshaping of non-target tissue adjacent the anchors. In addition, with less or no cinching, any undesirable effect on non-target tissue adjacent the connector is also minimized. On the other hand, should reshaping adjacent to the anchors and/or connector be desired, such reshaping can be achieved through a combination of expansion of the anchors and cinching of the connector between them. The cinching is performed as with prior devices: by anchoring a distal anchor, placing a proximally-directed force on a connector extending proximally from the distal anchor, and anchoring a proximal anchor before ceasing the proximally directed force to maintain the device's configuration and the reshaping of the tissue.

[0035] Figure 3 shows another embodiment of the invention. As in the embodiment of Figures 1 and 2, device 40 in Figure 3 has two anchors 42 and 44 connected by a connector 46. Connector 46 is formed as a ribbon, preferably from a shape memory material such as nitinol, with a focal deflector 48 formed therein. The anchors 42 and 44 may be formed like the anchors of the previous embodiment.

[0036] In use, device 40 is delivered via catheter to the treatment site in a collapsed or unexpanded configuration. Device 40 is then deployed by expelling it from the catheter and expanding it within a lumen in a position and orientation that places focal deflector 48 against the lumen's vessel wall adjacent to the target tissue to modify the shape of the target tissue. While the device may also be cinched to provide additional reshaping, the amount of cinching required will be less, thereby minimizing the reshaping of any non-target tissue adjacent the lumen by the connector. In addition, as with the previous

embodiment, anchors 42 and 44 do not need to be expanded as much, thereby minimizing the reshaping of the non-target tissue adjacent to the anchors.

[0037] Figures 4 and 5 show yet another embodiment of the invention and its use to treat mitral valve regurgitation. Device 50 has proximal and distal anchors 52 and 54 connected by a connector 56. Anchors 52 and 54 are preferably formed like the anchors of the embodiments of Figures 1-3.

[0038] A focal deflector 58 is disposed on connector 56. In this embodiment, focal deflector 58 has substantially the same design as anchors 52 and 54. Focal deflector 58 is formed from wire (preferably made from a shape memory material such as nitinol) and has a figure 8 configuration when expanded. A crimp 62 attaches the wire to the connector 56. The anchors and focal deflector are delivered via a catheter to the appropriate site within the lumen in an unexpanded configuration, then expanded to a deployed configuration through the application of actuation forces delivered by catheters or other known tools. Like the anchors, focal deflector 58 may be locked in its expanded configuration by advancing an eyelet 60 over a lock bump 61.

[0039] As shown in Figure 4, when disposed in a lumen such as the coronary sinus, the orientation of device 50 places focal deflector 58 against the coronary sinus wall adjacent the target tissue 59 of the mitral valve annulus 57 to reshape the mitral valve annulus. Device 50 may be curved to help ensure proper orientation. As with the other embodiments, because of the action of focal deflector 58, the desired reshaping of the mitral valve annulus may be achieved with less or even with no cinching. Thus, the anchors do not need to anchor as tightly and may be expanded less, thereby minimizing the reshaping of non-target tissue adjacent the anchors. In addition, with less or no cinching, the effect on non-target tissue adjacent the connector is also minimized.

[0040] Because it can be expanded and locked like an anchor, the focal deflector 58 of Figures 4 and 5 can also be used like an anchor during a cinching operation. For example, after expanding and locking distal anchor 54, a proximally-directed force can be exerted on the portion of connector 56 extending between distal anchor 54 and focal deflector 58 prior to expanding and locking focal deflector 58 to cinch the distal portion of device 50. Likewise, after expanding and locking focal deflector 58, another proximally-directed force can be exerted on the portion of connector 56 extending

between focal deflector 58 and proximal anchor 52 prior to expanding and locking proximal anchor 52 to cinch the proximal portion of device 50. If cinching is needed to achieve the desired shape modification of the target tissue, the presence of focal deflector 58 enables a user to cinch the distal and proximal portions of device 50 with different cinching forces.

[0041] The focal deflector shown in the embodiment of Figures 4 and 5 may have other orientations. For example, Figure 6 shows an embodiment in which the focal deflector 68 of device 60 faces in the same direction as the anchors 62 and 64. In addition, the focal deflector of the embodiments of Figures 4-6 may be self-expanding but not locking.

[0042] Figures 7 and 8 show yet another embodiment of the invention. Like the other embodiments, device 70 has a proximal anchor 72 and a distal anchor 74 connected by a connector 76. Disposed on connector 76 is a focal deflector 78 formed as an expanded cut-out tube, such as a modified stent.

[0043] As shown in Figure 7, device 70 may be deployed in the coronary sinus to treat mitral valve regurgitation by reshaping the tissue adjacent to focal deflector 78. Device 70 is delivered to in an expanded configuration to the treatment site, then expelled from the catheter. Anchors 72 and 74 self-expand, then are further expanded and locked as in the other embodiments. Focal deflector 78 may also self-expand to the configuration shown in Figures 7 and 8. Alternatively, focal deflector 78 may be expanded by using a balloon catheter to provide the actuation force, as is well-known in the stent art.

[0044] As in the other embodiments, because of the action of focal deflector 78, the desired reshaping of the mitral valve annulus may be achieved with less or even with no cinching. Thus, the anchors do not need to anchor as tightly and may be expanded less, thereby minimizing the reshaping of non-target tissue adjacent the anchors. In addition, with less or no cinching, the effect on non-target tissue adjacent the connector is also minimized.

[0045] Figure 9 shows an embodiment of a device 80 with proximal and distal anchors 82 and 84 with a figure 8 design like other embodiments connected by a connector 86. A focal deflector 88 is formed as a flattened area in connector 86. In this embodiment, connector 86 and focal deflector 88 are formed from shape memory material wire, such as nitinol. While Figure 9 shows connector 86 and focal deflector 88 as three discrete

straight segments, any or all of these elements may be have a curve. In any variation on the embodiment of Figure 9, however, the focal deflector 88 is straighter than the connector portions extending distally and proximally from it to the distal and proximal anchors, respectively. Device 80 may be delivered and deployed at the treatment site in the same manner as the embodiments described above.

[0046] Figures 10-12 show yet another embodiment of a device 90 with proximal and distal anchors 92 and 94 with a figure 8 design like other embodiments connected by a connector 96. A focal deflector 98 is also formed with a wire 100 (preferably made from a shape memory material such as nitinol) bent into a figure 8 pattern. As shown in more detail in Figures 11 and 12, instead of a wrapped wire or solid metal crimp, focal deflector 98 has a base 102 with two downwardly extending struts 104. The angular spread between struts 104 helps orient the device within the lumen. Base 102 may be made from a laser-cut shape memory material such as nitinol. The combination of the expansion of anchor wire 100 (as in the embodiment shown in Figure 6) with the downward pressure from struts 104 (as in the embodiments shown in Figures 1-3) provide for focal deflection of target tissue adjacent to the focal deflector.

[0047] As with other embodiments, device 90 may be delivered via a catheter and deployed in the coronary sinus to treat mitral valve regurgitation by reshaping the tissue adjacent to focal deflector 98. The device is in a deformed and unexpanded state within the catheter, and self-expands and reforms into the shape shown in Figure 10 once expelled from the catheter. The anchors 92 and 94 and the anchor portion 100 of focal deflector 98 are further expanded and locked by advancing their respective eyelets over corresponding lock bumps on their proximal sides.

[0048] Because of the action of focal deflector 98, the desired reshaping of the mitral valve annulus may be achieved with less or even with no cinching. Thus, the anchors 92 and 94 do not need to anchor as tightly and may be expanded less, thereby minimizing the reshaping of non-target tissue adjacent the anchors. In addition, with less or no cinching, the effect on non-target tissue adjacent the connector is also minimized. Furthermore, because focal deflector 98 is formed similar to an anchor, the presence of focal deflector 98 enables a user to cinch the distal and proximal portions of device 90 with different cinching forces.

[0049] The embodiment of Figure 13 omits the wire 100 of focal deflector 98 but is identical to the embodiment of Figures 10-12 in all other respects.

[0050] Figure 14 shows an embodiment of a device 110 with a proximal anchor 112 formed in a figure 8 pattern, as in other embodiments. A focal deflector 114 formed as an anchor in a figure 8 pattern, as in the embodiment of Figure 6, is connected to proximal anchor 112 by a connector 116. A tail 118 extends distally from focal deflector 114 formed from a wire bent in a loop. The loop has a circumference that allows the loop to engage the wall of the vessel in which the device is placed. The points of engagement between the loop and vessel depend on the relative diameters of the loop and vessel. When deployed in a curved vessel, such as the coronary sinus, the loop will follow the vessel's curve to orient the device correctly within the vessel. The ends of the wire are contained with a crimp 120. A small loop 122 is formed at the distal end of tail 118 to provide additional spring action to the tail.

[0051] As in the other embodiments, device 110 may be delivered via a catheter and deployed in the coronary sinus to treat mitral valve regurgitation by reshaping the tissue adjacent to focal deflector 114. The device is in a deformed and unexpanded state within the catheter, and self-expands and reforms into the shape shown in Figure 14 once expelled from the catheter. The proximal anchor 112 and focal deflector 114 are further expanded and locked by advancing their respective eyelets over corresponding lock bumps on their proximal sides.

[0052] Element 114 of device 110 in Figure 14 may be used as a distal anchor instead of as a focal deflector, of course.

[0053] Other modifications of the device are within the scope of the invention. For example, the anchors may be of some other design known in the art. In addition, the focal deflector may have some other shape designed to make the desired change in the target tissue.